

Appln. No. 10/538,927
Amd. dated December 11, 2007
Reply to Office Action of July 11, 2007

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1-4 and 8 presently appear in this application, with claim 8 being withdrawn by the examiner, in the above-identified application. Reconsideration and allowance are hereby respectfully solicited.

Rejoinder of claim 8 (Group II) is respectfully requested in view of the arguments below with regard to the applied Morgan et al. reference. Accordingly, claim 8 does indeed share a special technical feature with claims 1-4 of Group I.

Claims 1-4 have been rejected under 35 U.S.C. §112, first paragraph, because the examiner states that the specification, while being enabling for a method for treating non-ischemic heart failure comprising administering to a patient in need thereof a granulocyte colony-stimulating factor (G-CSF), does not reasonably provide enablement for any colony stimulating factor (CSF). This rejection is obviated by the amendment to claim 1 to recite "granulocyte-colony stimulating factor".

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

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Claims 1-5 and 9-11 have been rejected under 35 U.S.C. §102(b) as being anticipated by Cohen et al. (WO 98/27995). This rejection is respectfully traversed.

Cohen requires implanting myogenic precursor cells into a subject and treating the subject with a morphogen in combination with G-CSF. Claim 1 is now amended to recite that G-CSF is the "sole" active ingredient administered, as supported by the present specification at page 11, Experiment 1, lines 18-22. Accordingly, Cohen does not anticipate the presently claimed invention because Cohen does not administer G-CSF as the "sole" active ingredient.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1-5 and 9-11 have been rejected under 35 U.S.C. §102(b) as being anticipated by Morgan et al., *Clin. Cancer Res.* 3:2337-2345 (1997). This rejection is respectfully traversed.

Although Morgan discloses the therapeutic activity of G-CSF in patients with metastatic breast cancer, Morgan does not teach any therapeutic effect of G-CSF on congestive cardiomyopathy. No congestive cardiomyopathy had already occurred in the patients with metastatic breast cancer. This is quite clear from the disclosure in Morgan that patients may be safely treated with dose-intensive doxorubicin therapy without fear of unsuspected severe myofibrillar damage due to

anthracyclines (see page 2344, left column, end of first paragraph). Accordingly, Morgan does not treat patients with non-ischemic heart failure and therefore cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1, 2, 5 and 9 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 17 of copending application no. 10/924,197.

According to MPEP 804I.B.1, "[i]f a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer." (emphasis added)

As applicants believe that the above enablement and prior art rejections are obviated, this nonstatutory obviousness-type double patenting rejection over a later-filed application 10/924,197 is the only rejection remaining. Accordingly, this provisional obviousness-type double patenting rejection should be withdrawn to permit the present earlier-filed application to issue as a patent without a terminal disclaimer.

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Reconsideration and withdrawal of the rejection are
therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C.
§112 and define patentable subject matter warranting their
allowance. Favorable consideration and early allowance are
earnestly urged.

Respectfully submitted,

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